K080332
Page 1 of 2

Section 5
510(k) Summary

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1. Submitter

SEP - 5 2008

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4359
Fax: 508-683-5939

Contact: Ashley Pyle
Regulatory Affairs Specialist
Date Prepared: February 6, 2008

2. Device

Trade Name: Polyflex Esophageal Single-Use Stent System
Common Name: Prosthesis, Esophageal
Classification Name: Prosthesis, Esophageal
Regulation Number: 878.3610
Product Code: ESW
Classification: Class II

3. Predicate Devices

Polyflex Esophageal Single-Use Stent System, K030559

4. Device Description

The Polyflex Esophageal Stent System consists of a stent and delivery system. The stent is composed of a polyester braided material encapsulated with silicone. The stent has blue (endoscopic control) and black (fluoroscopic control) markers at both ends and in the center to aid with stent positioning. The delivery system is provided unassembled and consists of the following components:

- Delivery tube. Used to deliver the stent into the esophagus
- Stent Loader. With basket for loading the stent into the Delivery tube
- Wire Guide with Dilator and stent clamp. For atraumatic introduction of the Delivery tube into the esophagus using a guidewire
- Graduated Soft Positioner. Flexible aid with inner channel to deploy the stent from the Delivery tube
- Stopper. Aid for the temporary fixation of the Polyflex stent during the loading procedure into the Delivery tube.

5. Intended Use:

The Polyflex Esophageal Stent System is indicated for stenting:

- Esophageal stenoses, such as stenting refractory benign strictures and malignant strictures (resectable or nonresectable)
- Stenting esophago-respiratory fistulas
- Maintaining esophageal lumen patency in esophageal strictures caused by intrinsic or extrinsic tumors

6. Technological Characteristics:

The proposed Polyflex Esophageal Stent System has identical technological characteristics (materials, construction, manufacturing processes) as the currently marketed Polyflex Esophageal Stent System.

7. Performance Data:

This is a request to clarify the indication for *stenting of esophageal stenoses (strictures), such as stenting refractory benign strictures and/or malignant strictures,* by including *resectable or non-resectable* strictures. No new materials or design changes were introduced. Therefore, the performance testing presented in 510(k) K030559 was not repeated.

8. Conclusion:

The proposed Polyflex Esophageal Stent System is substantially equivalent to the currently marketed Polyflex Esophageal Stent System. BSC is requesting to clarify the indication for, *stenting of esophageal stenoses (strictures), such as stenting refractory benign strictures and/or malignant strictures,* by adding *resectable and non-resectable* strictures, in order define the stricture types, which are within the currently cleared indication, but not explicitly stated,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2008

Ms. Ashley Pyle
Regulatory Affairs Specialist
Boston Scientific Corporation
Endoscopy Division
100 Boston Scientific Way
MARLBOROUGH MA 01752-1234

Re: K080332
Trade/Device Name: Polyflex™ Single-Use Esophageal Stent System
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: ESW
Dated: August 28, 2008
Received: August 29, 2008

Dear Ms. Pyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4
Indications for Use Statement

Indications for Use:

510(k) Number (if known): **K080332**

Device Name: **Polyflex Single-Use Esophageal Stent System**

Indications for Use:

Stenting:

- Esophageal stenoses (strictures), such as stenting refractory benign strictures and/or malignant strictures (resectable and non-resectable)
- Stenting esophago-respiratory fistulas
- Maintaining esophagus lumen patency in esophageal strictures caused by intrinsic or extrinsic tumors

Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Part D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080332